



CASE 4:01-158A/PCT

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IN RE NATIONAL STAGE APPLICATION OF  
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Art Unit: 1615

Examiner: R.M. Joynes

INTERNATIONAL APPLICATION NO: PCT/EP 00/09455

FILED: 27 SEPTEMBER 2000

U.S. APPLICATION NO.: 10/089,265

35 U.S.C. §371 DATE: 27 MARCH 2002

FOR: ORAL CONTROLLED RELEASE FORMULATIONS

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

TERMINAL DISCLAIMER

Sir:

Novartis AG, a company organized under the laws of the Swiss Confederation, having a place of business at Lichtstrasse 35, Basel, Switzerland 4058, represents that it is the assignee and owner of the entire interest in the above-identified application by virtue of an assignment, a copy of which is attached hereto. It should be noted that the "original" of the assignment will be transmitted for recordation in the United States Patent and Trademark Office (PTO) in due course.

Novartis AG hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §154-156 and §173, as presently shortened by any terminal disclaimer, of prior U.S. Patent No. 6,565,883, issued May 20, 2003. Said U.S. Patent No. 6,565,883 is also assigned to Novartis AG by virtue of an assignment which was recorded in the PTO on March 21, 2003 at Reel 013877/Frame 0214.

09/02/2003 EFLORES 00000112 190134 10089265

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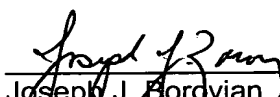
Novartis AG hereby agrees that any patent granted on the above-identified application shall be enforceable only for and during such period that it and prior U.S. Patent No. 6,565,883 are commonly owned. This agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assigns.

In marking the above disclaimer, Novartis AG does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. §154-156 and §173 of prior U.S. Patent No. 6,565,883, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321, has all claims cancelled by a re-examination certificate, is re-issued, or is in any manner terminated prior to the expiration of its fully statutory term as presently shortened by any terminal disclaimer.

A terminal disclaimer fee under 37 CFR §1.20(d) is included.

Signed this 28<sup>th</sup> day of AUGUST, 2003 by the undersigned agent of record.

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Encls.: Copy of Assignment

Date: August 28, 2003